

# **System Level Manual**

Regulatory Standards Division, AMA-200

Document #

QP 211

Revision Original

Title:

**Management Review Procedure** 

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REVISION HISTORY				
Rev	Description of Change	Author	Effective Date	
А	Original	JLA	06/03/2003	

REFERENCE DOCUMENTS				
Document Number	Document Title			
QMS 200	AMA-200 Quality System Manual			

Documents referenced in this procedure are applicable to the extent specified herein.

### 1. Purpose

The purpose of this document is to define the management review process of the AMA-200 quality system by the AMA-200 Leadership Team.

## 2. Scope

The management review process of the AMA-200 Quality System.

## 3. Definitions and Acronyms

QMS 200.

### 4. Flowchart

A flow chart is not required for this document.

### 5. Responsibilities

See the below "Procedure" section for specific responsibilities.

#### 6. Procedure

- 6.1 The Regulatory Standards Division Management Representative shall:
  - 6.1.1 Coordinate the Quality Management Review.
    - 6.1.1.1 Quality Management Review meetings shall include attendance of all AMA-200 Management personnel or their designees:
      - 6.1.1.1.1 Division Manager.
      - 6.1.1.1.2 ISO 9000 Management Representative.
      - 6.1.1.1.3 Asst. Division Manager.
      - 6.1.1.1.4 Branch Managers.



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6.1.1.1.5 PAACE representative if required.

- 6.2 Quality Management Review meeting agendas shall include the following:
  - 6.2.1 Review past and current performance and look for improvement opportunities in the following areas:
    - 6.2.1.1 Audit results, including audit schedule and progress
    - 6.2.1.2 Metrics defined in previous meeting(s)
    - 6.2.1.3 Customer feedback
    - 6.2.1.4 Conformance of the product and observation of the process
    - 6.2.1.5 Preventive and corrective actions
    - 6.2.1.6 Open and follow-up actions of previous reviews
    - 6.2.1.7 Changes that could affect the QMS
    - 6.2.1.8 Ways to improve the QMS
      - 6.2.1.8.1 Include the review of the AMA-200 Quality Policy and Objectives for continuing relevance.
  - 6.2.2 The results of the management review shall consist of any decisions and/or actions related to:
    - 6.2.2.1 Quality Management System improvement
    - 6.2.2.2 Product improvement
      - 6.2.2.2.1 Include the need to revise existing procedures, which are synonymous with quality control plans.
    - 6.2.2.3 Provision of resources
    - 6.2.2.4 Records of reviews
- 6.3 Ensure minutes of the Quality Management Review meetings are recorded and that the status of assigned action items is tracked.
- 6.4 In addition to the minutes of the review, a Management Review Checklist, QF 211.01, must be completed. This checklist is self-explanatory and includes an area for comments.

#### 7. Metrics

Metrics for this document will be a product of the Management Review Process performed by the AMA-200 Leadership Team.



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## 8. Quality Records

Quality Records required for this document are listed in the table below. These records shall be generated and managed in accordance with AMA-200 Quality Records procedures.

Verifying Document Type or Number	Title	Retention Time
Recorded Minutes	Minutes of meeting	Five Years
QF 211.01	Management Review Checklist	Five Years

Quality documents, in blank form, are found in Appendix 1 of the AMA-200 QSM.